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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,025	04/24/2001	Judith Aronhime	1662/52602	6176

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EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/25/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841,025

Applicant(s)

ARONHIME ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 161-166 and 262-279 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 261 and 262 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Claims 161-166, 261-279 are pending. Claims 124-160, 167-260 have been canceled according to the amendment filed on 3-31-2003.

Claim Rejections - 35 USC § 112

2. The cancellation of Claims 248-250, 252-254, 256-258 has rendered moot the 112 second paragraph rejection.

Claim Rejections - 35 USC § 103

3. The rejection under 35 U.S.C. 103(a) as being unpatentable over Ettema I (6281360) in view of Ettema II (6242460, PTO-1449) is rendered moot by the cancellation of the rejected claims.
4. The rejection under 35 U.S.C. 103(a) as being unpatentable over Ettema I (6281360) in view of Ettema II (6242460, PTO-1449) and further in view of Lee (5271944, PTO-1449) and/or Bernini (4332721, PTO-1449) is rendered moot by the cancellation of the rejected claims.
7. The rejection under 35 U.S.C. 103(a) as being unpatentable over Benincasa (5891891, PTO-1449) in view of Kaplan (4382938, PTO-1449) and Wall, 'Pharmaceutical applications of drug crystal studies', PTO-1449) is rendered moot by the cancellation of the rejected claims.
8. The rejection under 35 U.S.C. 103(a) as being unpatentable over Benincasa (5891891, PTO-1449) in view of Kaplan (4382938, PTO-1449) and Wall, 'Pharmaceutical applications of drug crystal studies', PTO-1449) and further in view of Lee (5271944, PTO-1449) and/or Bernini (4332721, PTO-1449) is rendered moot by the cancellation of the rejected claims.

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Claim Rejections - 35 USC § 102

9. The rejection under 35 U.S.C. 102(b) as being anticipated by Benincasa (5891891, PTO-1449) is maintained for claim 165. The rejection is applicable to new composition claims 273-278. Benincasa's pharmaceutical composition comprising Zolpidem hemitartrate (column 2, lines 15-25) would be the same as the instant liquid composition comprising a Zolpidem hemitartrate of a particular size, Form D hydrate or solvate in a particular size, since the optionally micronized hydrate or solvate form of the instant would no longer exist in solution.

Claim Rejections - 35 USC § 112(2)

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 161-166, 263-279 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In base claim 161, the term 'about' in 'having peaks about...' is indefinite since there is no indication as to what range of specificity is covered by the term 'about' in the specification. The rejection is applicable to claims dependent on 161.

Claim Rejections - 35 USC § 112(1)

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 161-166, 263-279 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification only discloses a zolpidem hemitartrate *form D* having the X-ray powder diffraction pattern having peaks at 7.1, 9.5, 14.1, 19.6 and 24.5 plus or minus 0.2 degrees two-theta, which is a monohydrate or hemiethanolate (page 18 of the specification). The zolpidem hemitartrate having the X-ray powder diffraction pattern having peaks at 7.1, 9.5, 14.1, 19.6 and 24.5 plus or minus 0.2 degrees two-theta as recited in the amended claim 161, the hydrate and solvate thereof as recited in new claims 263, 268, and the compounds in the claims dependent thereof, are not found in the specification.

Allowable Subject Matter

12. Claims 261, 262 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

While Zolpidem hemitartrate in the form of hydrate or solvate is described by Ettema I and II, Form D with the specific X-ray powder diffraction pattern as recited in the instant claims is not taught or suggested by the prior art of record.

Drawings

13. New corrected drawings are required in this application. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read "Evelyn Huang", is written over the printed name.

Evelyn Huang

Primary Examiner

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August 22, 2003